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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/573,385

05/07/2007

Tomoki Hamamoto

2006\_0434A

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04/01/2010

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EXAMINER

EPPS -SMITH, JANET L

ART UNIT

PAPER NUMBER

1633

NOTIFICATION DATE

DELIVERY MODE

04/01/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/573,385	<b>Applicant(s)</b> HAMAMOTO ET AL.	
	<b>Examiner</b> Janet L. Epps-Smith	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-10 are presently pending for examination.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 102***

3. Claim 1-2, 4-5 and 8 remain rejected under 35 U.S.C. 102(b) as being anticipated by Simon et al. (JACS, 1988, Vol. 110, pages 7159-7163, see IDS).
4. Applicant's arguments filed 12/08/2009 have been fully considered but they are not persuasive. Applicants traversed the instant rejection on the grounds that in contrast to the presently claimed invention, "the process of Simon et al., CMP-NeuAc is purified by use of NH<sub>4</sub>OH, ethanol, etc., followed by the addition of phosphatase and MgCl<sub>2</sub>, and then the addition of ethanol (the second addition). Such a process is different from the claimed invention, which requires addition of a divalent cation species during the initial stage of purification." Applicant's arguments are not persuasive since the instant claims have been amended to recite wherein step (2) can be practiced before step (1) which comprises the addition of divalent cation. As stated in the prior Office Action, the method of Simon et al. clearly encompasses a method for purifying CMP-N-NeuAc wherein the method comprises the steps of (1) adding a divalent cationic species, namely MgCl<sub>2</sub>, (2) adding a phosphatase to the CMP-N-NeuAc solution, (3) adding an organic solvent, ethanol and (4) Collecting the precipitated CMP-NeuAc, (5) steps (3)-

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(4) are repeated. Furthermore, the methods of Simon et al. are disclosed as producing CMP-NeuAc at greater than 90% purity.

***Claim Rejections - 35 USC § 103***

5. Claims 1-10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Simon et al. in view of Warren et al. and Vann et al.

6. Applicant's arguments filed 12/08/2009 have been fully considered but they are not persuasive. Applicants traversed the instant rejection on the grounds that one skilled in the art, such as Simon, would not expect that the simple precipitation method of the claimed invention could produce CMP-NeuAc that is 95% or more pure, without the use of purification steps such as chromatography. Applicants have not provided any evidence to support their assertion of unexpectedly high purity of CMP-NeuAc commensurate in scope with the entire breadth of the claimed invention. As per MPEP § 716.01(c)[R-2]II. "[T]he arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant."

Absent evidence to the contrary, it would have been obvious to the ordinary skilled artisan at the time of the instant invention to modify the teachings of Simon et al. in view of Warren et al. and Vann et al. in the design of the instant invention. One of

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ordinary skill in the art would have been motivated to make this modification since the prior art clearly teaches that the enzyme that catalyzes the formation of CMP-NeuAc requires a divalent cation for activity, and further wherein the divalent cation includes manganese ion. Additionally, it would have been obvious to substitute one equivalent divalent cation (see that process of Simon et al. utilizes  $\text{MgCl}_2$ ) for another (i.e. or  $\text{Mn}^{+2}$ ) as taught by Vann et al., with the expectation of producing a similar result. See MPEP § 2144.06[R-6]II. SUBSTITUTING EQUIVALENTS KNOWN FOR THE SAME PURPOSE.

***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/  
Primary Examiner, Art Unit 1633